K093554

510(k) Summary

APR 13 2010

Applicant:

Edwards Lifesciences, LLC
One Edwards Way
Irvine, CA 92614
USA
Phone: 949.250-3837
Fax: 949.756-4408

Date:

November 3, 2009

Contact Persons:

Jason K. Lyon
Principle Project Manager, Regulatory Affairs

Dean Knight
Sr. Director of Regulatory Affairs

Proprietary Device Name:

RetroFlex™ Dilator Kit

Common Device Name:

Vessel dilator for percutaneous catheterization
(21 CFR 870.1310, Product Code DRE)

Classification:

Class II

Predicate Devices:

Estech – Estech Percutaneous Dilator Insertion Kit
cleared under K070749

Maxxim Medical, Inc – Vessel Dilator
cleared under K963388

Spectranetics Corporation – Visisheath™ Dilator Sheath
cleared under K092378

Manufacturer:

Edwards Lifesciences, LLC
One Edwards Way
Irvine, CA 92614
USA

7.1 *Substantially Equivalent To:*

The RetroFlex Dilator Kit is substantially equivalent to the predicate devices in intended use, design, specifications, packaging, and sterilization. For each predicate device there are slight variations, yet do not fundamentally change the scientific technology of the devices, which is to dilate vessels for introducing intravascular devices. A summary of equivalency is in Section 11.4 below.

7.2 *Description of the Device Subject to Premarket Notification:*

The RetroFlex Dilator Kit offers a variety of sizes and is packaged as either a 4-piece set or a 7-piece set. The dilators are made of polyethylene (LDPE and HDPE) with 20% barium sulfate and 1% titanium dioxide to aid in visualization under fluoroscopy.

The RetroFlex Dilator Kit is heat-treated and a one-piece mold with a formed tip. The distal tip is tapered with an inner lumen for tracking a .035" guidewire. The hub on the proximal end is bonded with an adhesive, and the dilators are hydrophilic coated to allow smooth arterial dilation. The device is sold and packaged sterile as a 4-piece or 7-piece kit (**Table 7.2.1**).

Table 7.2.1 – RetroFlex Dilator Kits

Dilator Kit Set	Dilator Sizes
4-piece dilators	16F, 18F, 20F, and 22F
7-piece dilators	16F, 18F, 20F, 22F, 23F, 25F, and 28F

7.3 *Indications For Use:*

The RetroFlex Dilator Kit is intended for use in dilation of the peripheral vasculature.

7.4 *Device Safety and Performance Data:*

The RetroFlex Dilator Kit was verified and tested according to performance testing standards ISO 10555-1:1997, Sec 4.5, *Sterile Single Use Intravascular Catheters.* The following tests have been conducted to demonstrate safety and effectiveness with respect to intended use, design, materials, and performance.

- Visual Examination
- Dimensional Verification
- Tensile Strength (Hub/Shaft)
- Guidewire Compatibility Test
- Hydrophilic Coating (Friction) Test
- Packaging Integrity
- Product Shelf Life
- Sterilization Validation
- Biocompatibility
    - Medium Eluate Method (MEM)
    - Agar Overlay Method (AO)
    - Blood Compatibility Test Method
    - Mouse Systemic Injection
    - Rabbit Intracutaneous Irritation
    - Guinea Pig Maximization Test
    - Complement Activation Test

- Microbiology
  - Endotoxin-Mediated Pyrogenicity

- Chemical
  - Material Verification
  - USP Physico-Chemical Test for Plastic Closures
  - Non-Volatile Residues Test

7.5 Conclusion:

Based upon the non-clinical testing noted above and in this 510(k) application, the RetroFlex Dilator Kit meets the required standards and has demonstrated that it is as safe and performs as well as the predicate devices listed in this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 13 2010

Edwards LifeSciences, LLC
c/o Jason Lyon
One Edwards Way
Irvine, CA 92614

Re: K093554
Trade/Device Name: RetroFlex Dilator Kit
Regulation Number: 21 CFR 870.1310
Regulation Name: Dilator, vessel, for percutaneous catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: March 19, 2010
Received: March 22, 2010

Dear Mr. Lyon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. Statement of Indications for Use

Indications for Use

510(k) Number (if known): K093554

Device Name: RetroFlex™ Dilator Kit:

The RetroFlex™ Dilator Kit is intended for use in dilation of the peripheral vasculature.

Prescription Use___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093554